

Message Text

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PAGE 01 STATE 181084
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 MED-03 COME-00 /029 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: RFISCHER
EUR/CE:SKLINGAMAN (INFO)
EUR/WE:EBEIGEL(INFO)

-----050651 022057Z /65

P 022022Z AUG 77
FM SECSTATE WASHDC
TO AMEMBASSY BERN PRIORITY
AMEMBASSY PARIS

UNCLAS STATE 181084

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, FR, SZ

SUBJECT: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE
(RECALL T-123-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: COBE HEMAFLO BLOOD TUBING SET - A BLOOD
TUBING SET FOR USE WITH AN ARTIFICIAL KIDNEY (HEMODIALYZER).

PRODUCT IDENTIFICATION: BRAND NAME IS "COBE" ON ALL SETS
INVOLVED. EACH SET IS LABELED IN PART "XXCOBE HEMAFLO
BLOOD TUBING SET FOR HEMODIALYSIS THIS SET CONSISTS OF ONE
ARTERIAL AND ONE VENOUS TUBING SEGMENT WITH VENOUS DRIP
CHAMBER STERILE/NONPYROGENIC FLUID PATHWAY - FEDERAL LAW
(U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER
OF A PHYSICIAN - SEE ENCLOSED INSTRUCTIONS PRIOR TO USE -
INTENDED FOR SINGLE USE ONLY COBE LABORATORIES, INC. 1201
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PAGE 02 STATE 181084

OAK STREET, LAKEWOOD, COLORADO 80125 U.S.A. (303)
232-6800XXX".

MANUFACTURER/RECALLING FIRM: DEVICE IS MANUFACTURED AND
ASSEMBLED BY COBE LABORATORIES, INC., 1201 OAK STREET,
LAKEWOOD, COLORADO 80215. RECALL IS BEING HANDLED THROUGH
THE MAIN OFFICE AT THE ABOVE ADDRESS.

2.

REASON FOR RECALL: BETWEEN APRIL 6, 1977 AND MAY 3, 1977, THE FIRM RECEIVED APPROXIMATELY 10 COMPLAINTS ON LOT 01E-615, 10 COMPLAINTS ON LOT 01E614, AND 1 COMPLAINT ON LOT 02E543 OF LEAKAGE DUE TO SEPARATION OF BONDS WHERE TUBING IS INSERTED INTO THE REDUCERS. LEAKAGE IN THE 3 LOTS HAS BEEN VERIFIED BY COBE TESTING. THE COMMON FACTOR IN ALL 3 LOTS IS A SINGLE INDIVIDUAL INVOLVED IN CEMENTING THE BONDS. THERE IS NO FURTHER EVIDENCE OF LEAKAGE IN LOTS MANUFACTURED BEFORE OR AFTER THE ABOVE 3 LOTS AS TESTED BY COBE. WHILE THERE HAVE BEEN NO FATALITIES, THERE WERE SEVERAL CASES OF BLOOD LOSS.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THEY HAVE RECEIVED LETTER AND/OR TELEX FROM COBE REGARDING RECALL AND DISPOSITION OF AFFECTED LOTS.

4. FOREIGN CONSIGNEES AS FOLLOWS:

COBE S.A.
55 AVENUE DU CENTENAIRE
94210 LA VARENNE
FRANCE

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PAGE 03 STATE 181084

A. BOLLINGER
MEDISCHE ELECTRONIK UND TECHNIK
FORCHSTRASSE 4
CH - 8610 USTER
SWITZERLAND CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALL
Control Number: n/a
Copy: SINGLE
Sent Date: 02-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE181084
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770276-1144
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197708105/aaaadlff.tel
Line Count: 99
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 8cab144f-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 03-Nov-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1414993
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE (RECALL T-123-7)
TAGS: OGEN, ETRD, EIND, TBIO, FR, SZ
To: BERN PARIS
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/8cab144f-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009